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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/001,725	10/22/2001	Kevin Pan	ORT-1517	7498

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EXAMINER

HUANG, EVELYN MEI

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 02/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/001,725

Applicant(s)

PAN ET AL.

Examiner

Evelyn Huang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 6 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 10-15 is/are rejected.
- 7) ☒ Claim(s) 5,7-9 and 16-18 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 5, 9, and claims 1-4, 7-8, 10-18 in part, drawn to a compound wherein X is CH, or C(C₁-C₆alkyl), R³ is aryl, aralkyl, classified in class 546, subclass 226, the composition and method of use thereof.
 - II. Claims 1-4, 7-8, 10-18 in part, drawn to a compound not included in group I, wherein X is CH, or C(C₁-C₆alkyl), R³ is other than aryl, aralkyl, classified in class 546, subclass 194, the composition and method of use thereof.
 - III. Claim 6, and claims 1-4, 7-8, 10-18 in part, drawn to a compound wherein X=N, R³ is aryl or aralkyl, classified in class 544, subclass 358, the composition and method of use thereof.
 - IV. Claims 1-4, 7-8, 10-18 in part, drawn to a compound not included in group III, wherein X=N, R³ is other than aryl or aralkyl, classified in class 544, subclass 360, the composition and method of use thereof.
2. The inventions are structurally, chemically and patentably distinct, and have acquired a separate status in the art as shown by their different classification. A reference anticipating a aryl-piperidinyl compound of group I would not render obvious the heteroaryl-piperidinyl or the aryl-piperazinyl or heteroaryl-piperazinyl compound of groups II to IV. The search is not co-extensive and is therefore burdensome. Since the search required for one group is not required for the other groups, restriction for examination purposes as indicated is proper.
3. During a telephone conversation with Ms. Appollina on 1-21-2003 a provisional election was made with traverse to prosecute the invention of group I, claims 5, 9, and claims 1-4, 7, 8, 10-18 in part. The species elected is compound 10 (page 87, Table 2). Affirmation of this election must be made by applicant in replying to this Office action. Claims of the groups II-IV

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inventions are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The method claim 14 is improperly dependent on the composition claim 10.

Duplicate Claims

6. Claim 11 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 10, drawn to a pharmaceutical composition comprising a compound of claim 1 and a pharmaceutically acceptable carrier. Claim 11 is drawn to a pharmaceutical composition made by mixing a compound of claim 1 and a pharmaceutically acceptable carrier, which has the same scope as claim 10, although not specifically recited, has to be made by mixing a compound of claim 1 and a pharmaceutically acceptable carrier as recited in claim 11. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

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Claim Rejections - 35 USC § 103

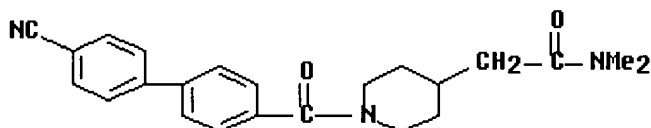
7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-4, 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Himmelsbach (5736559, PTO-1449).

NO BIOLOGICAL ANALYSIS

Himmelsbach generically discloses an aggregation-inhibiting compound and the composition thereof (columns 1-2). A specific example, having the following structure is described (column 34, Example 1 (6)).



Himmelsbach's compound has methyl whereas the instant has ethyl, propyl or benzyl on the amido nitrogen as R¹ and R². Himmelsbach, however, teaches that methyl, ethyl, propyl, isopropyl and benzyl are optional choices within a small genus of compounds (column 2, line 33; lines 50-53).

At the time of the invention, one of ordinary skill in the art would be motivated to replace Himmelsbach's methyl with the homologous ethyl, isopropyl or propyl, or the alternative benzyl to arrive at the instant invention with the reasonable expectation of obtaining an additional compound useful for inhibiting platelet aggregation since Himmelsbach had clearly taught that any species within the disclosed genus would be effective as anti-aggregation agent.

The compound of instant claims 2, 3 has amino instead of Himmelsbach's cyano on the terminal phenyl. Himmelsbach, however, teaches that cyano and amino are optional choices (column 1, line 43).

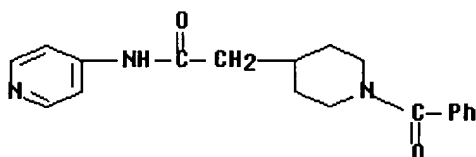
At the time of the invention, one of ordinary skill in the art would be motivated to replace Himmelsbach's cyano with the alternative amino to arrive at the instant invention with the

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reasonable expectation of obtaining an additional compound useful for inhibiting platelet aggregation since Himmelsbach had clearly taught that any species within the small disclosed genus would be effective as anti-aggregation agent.

9. Claims 1-3, 10-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sugimoto (4895841).

Sugimoto generically discloses a acetylcholine-esterase inhibiting cyclic amine compound and the composition thereof (columns 2-3). Specific compounds are described on columns 55-56 (Table 4, compounds 48-50). Compound 49 has the following structure.



Sugimoto's example compound 49 does not have the instant $(L^2)_n-R^4$ substituent, such as phenylmethoxy, on the phenyl.

However, Sugimoto teaches that the presence or absence of substituents on the phenyl is an optional choice (column 8, line 39 to column 9, line 1), an example of phenylmethoxy-substituted phenyl is shown on columns 107-108, Example 237.

At the time of the invention, one of ordinary skill in the art would be motivated to replace Sugimoto's unsubstituted phenyl with the alternative, exemplified phenylmethoxy-phenyl to arrive at the instant invention with the reasonable expectation of obtaining an additional compound useful for inhibiting acetylcholinesterase since Sugimoto had clearly taught that any species within the disclosed genus would be effective in the inhibition of acetylcholine esterase and thereby useful for treating CNS disorder such as dementia.

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Allowable Subject Matter

10. Claims 5, 7-9, 16-18 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The instant compound differs from Himmelsbach's compound (see paragraph 8 above) in having a different R2 and R4. Motivation to modify Himmelsbach's compound via multiple changes to arrive at the instant invention is lacking.

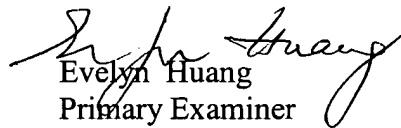
The instant compound differs from Sugimoto's compound (see paragraph 9 above) in having a different L². Motivation to modify Sugimoto's compound to arrive at the instant invention is lacking.

The method of using the inventive compound to treat depression and anxiety is not taught or suggested by Himmelsbach or Sugimoto.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Evelyn Huang whose telephone number is 703-305-7247. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on 703-308-4698. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.


Evelyn Huang
Primary Examiner
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January 30, 2003